PATENT SPECIFICATION

(11) 1 300 449

DRAWINGS ATTACHED

1 300 449

(21) Application No. 13828/70 (22) Filed 23 March 1970
(31) Convention Application No. 809 536 (32) Filed 24 March 1969 in
(33) United States of America (US)
(45) Complete Specification published 20 Dec. 1972
(51) International Classification A61B 17/18
(52) Index at acceptance
A5R X4
C3P 10A 10C13C 10C14B 10C4A 10C6A 10C8A 10C8C 10D4A 10T1X
F2H 11A3A 15 17U

(54) APPLIANCE FOR SURGICAL IMPLANTATION FOR BONE FRACTURE FIXATION

(71) We, THE METHODIST HOSPITAL, a corporation organized under the laws of the State of Texas, United States of America, of 6516 Bertner Boulevard, Houston, Texas 77025, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

Some corrosion has been found in supposedly corrosion resistant appliances such as a femur pin and plate which have been implanted in humans. After being in vivo for a period of time, the appliances in individuals suffering from sufficient pain to justify the removal of the pin and plate were found to have corrosion on the plate and the screws which secured the plate to the bone. Such corrosion in most cases investigated appears to have originated at a point on the contacting surfaces of the screws and the plate.

The present invention relates to an improved corrosion resistant appliance suitable for implanation in human bodies for bone fracture fixation.

An object of the present invention is to provide an improved bone fracture fixation appliance which avoids abrasive contact between the appliance and the screws during implantation.

In the accompanying drawings Figure 1 is a partial sectional view of a femur with an appliance attached thereto including a pin for securing the head of the femur.

Figure 2 is a partial detail sectional view of an appliance of the prior art showing the location of corrosion which has been observed.

Figure 3 is a partial detail sectional view of one form of improved appliance in accordance with the present invention.

Figure 4 is another partial detail sectional view of a modified form of an appliance in accordance with the present invention.

Figure 5 is an exploded view partly in section of another modified form of appliance in accordance with the present invention.

For human implantation, the material often used in appliances has been a type of stainless steel. However, even such stainless steel has been subject to corrosion when implanted and exposed to body fluids over a long period of time. Corrosion of implanted appliances not only may be sufficiently painful to suggest its removal but may deposit corrosion poducts in the surrounding tissues. It is, therefore, desirable that such corrosion be eliminated.

According to the invention, there is provided an implantable bone fracture fixation appliance comprising a corrosion resistant metal plate, a corrosion resistant metal screw, said plate having a bore therethrough to receive said screw, and an inert load bearing washer positioned between load transmitting surfaces of said screw and said plate whereby when said screw is tightened into bone, said washer remains between said surfaces and transmits the loading and prevents abrasion of the load transmitting surfaces when the screw is tightened into the bone.

The present invention also provides an appliance suitable for surgical implantation for bone fracture fixation comprising a corrosion resistant metal plate, and a corrosion resistant metal screw, said plate having at least one bore therethrough to receive said screw, and an annular inert load bearing washer bonded to said plate or said screw at a position to transmit the load between said plate and said screw and prevent abrasion of load transmitting surfaces of the plate and screw when said screw is tightened into bone.

Such corrosion has occurred in appliances on the engaging surfaces between the heads of screws and a plate which they are securing to a bone. As shown in Figures 1 and 2, a corrosion resistant metal plate 10 which supports a pin 12 is secured to the bone 14

by corrosion resistant metal screws 16. The plate 10 has a bore 18 for each of the screws 16 and the countersinks 20 surround such bores. The countersinks 20 provide the shoulders against which the heads of the screws 16 are adapted to engage. This illustrated appliance is an example of the type of stainless steel appliance in which corrosion has been found following a period of residence within a human body.

Figure 2 illustrates the location of the corrosion which has been found in such appliances. Such corrosion has been found on the engaging surfaces of countersink 20 and the screw shoulder 22. Such corrosion is believed to be caused by the breaching of the outer oxide layers of the metal in both the screw and plate by the tightening of the screw. Such breaching occurs at a position and under conditions in which oxidation is subsequently inhibited thereby allowing crevice corrosion to take place.

To eliminate this corrosion, an appliance in accordance with an embodiment of the present invention includes a suitable member to be interposed between the engaging surfaces of the screw shoulder 22 and the countersink 20 to thereby prevent the breaching of the outer oxide layers of the screw 16 and the plate 10 during tightening of the screw. The member which is suitable for this purpose must be suitably inert to the action of body fluids and must not cause any irritation or reaction of the body tissues. Further, this member must be placed in the proper position between the load transmitting surfaces and remain in such position when the screws 16 are being tightened to load the plate 10 sufficiently to secure the appliance in the desired position. Further such member must have a composition which will transmit these securing loads without being extruded out of position.

An improved member in accordance with the present invention is fashioned in the shape of a frusto-conical washer as shown in Figures 3, 4 and 5. In the form illustrated in Figure 3, the washer 24 is bonded by bonding material 26 to the shoulder 22 of screw 16 and when screw 16 is tightened in the bone 14, the washer 24 is retained in the position between shoulder 22 and countersink 20. The preferred materials of washer 24 and bonding material 26 we hereinafter set forth.

The structure illustrated in Figure 4 is similar to the structure shown in Figure 3 except that a washer 28 is bonded by bonding material 30 to the countersink 20. In some cases the bonding of the load transmitting washer may not be necessary and the structure illustrated in Figure 5 may be used. The washer 32 is frusto-conical and adapted to be positioned between the shoulder 22 of screw 16 and the countersink 20 of plate 10. Such washer 32 is made from the material hereinafter described.

It has been discovered that by proper preparation of the material of the washer that all of the aforementioned qualities are provided. For the washers, it is preferred that the basic material be polytetrafluoroethylene resin such as that marketed by DuPont under the trademark Teflon-7 TFE resin, Teflon-6 TFE resin and Teflon-1 TFE resin and especially prepared as herinafter described. The bonding of the washer is preferred to be achieved by fluorinated ethylene propylene which is marketed by DuPont as Teflon FEP resin. This bonding material is suitable for bonding the washer in its preselected position.

The bonding of the washer by the FEP resin is preferably achieved in a mold which has the shape to deform the washer to the shape of the part on which it is to be fused. At molding temperaures, the FEP melts and fuses the washer to the metal. It is preferred that the bonding conditions be at a temperature between 570 to 650°F., at a compression between 300 to 700 p.s.i. and that a three to ten minute soak at mold temperature and compression be provided. Bonding under such conditions has proven to be satisfactory.

The member or washer material, polytetrafluoroethylene, has incorporated therein reinforcing materials such as particulate metal, fibrous metal, fibrous glass, fibrous quartz or single crystalline filaments or whiskers. It is preferred that the reinforcing material be from 15% to 50% by volume of the material of the washer and that the tetrafluoroethylene polymer be from 85% to 50% by volume of the material of the washer.

The washer material is prepared by mixing the polymer and the reinforcing ingredients which may be one or more of the following: graphite, stainless steel, and cobalt alloy powders and glass fibres. In this mixing a suitable organic solvent is used such as Stoddard Solvent (a moderately volatile hydrocarbon analogous to kerosene). The mixing is in a very high speed, high shear mixer. In such mixing the proportion of solvent to dry ingredients is adjusted to the size of the mixer. For example, in a mixer of 500 milliliters, 375 milliliters of solvent were used for dry ingredients weighing approximately 50 grams. Mixing is carried out until a completely uniform slurry is produced.

The mixed slurry is filtered. The filtration is preferred to be by vacuum filter such as Buechner funnel, and should proceed until the residual solvent left in the filter cake is less than approximately 20% by weight.

Following filtration, the filter cake is placed between the platens of a heated press and is compressed at levels of from 500 to

3,000 p.s.i. and at a temperature of 170°F. for periods from one to five minutes. The conditions are adjusted so that the solvent level after compression is between six and ten percent by weight.

Next, the compressed filter cake is run through the nip of heated rolls which are heated to a temperature between 200 to 220°F. The thickness of the cake is reduced in decrements of approximately twenty thousandths of an inch to a thickness between twenty and eighty thousandths of an inch.

When the desired thickness is reached, the temperature of the rolls is elevated to between 320 and 360°F. and the thickness of the material during each subsequent pass is reduced to one-half its thickness. To maintain the desired thickness, the sheet of material is doubled after each pass and then is run through the next pass at ninety degrees to the previous pass. This procedure may be carried out from four to eight times depending on the apparent toughness of the product at a given stage of rolling.

When the rolling is completed, the material is sintered at a temperature from 640 to 660°F. for periods from thirty minutes to several hours depending on the thickness of the stock. It should be noted that if the product contains residual solvent which is slow to evaporate, extended periods of drying at temperatures from 300 to 400°F. may be required.

Following is a typical example of a material prepared which was found suitable for use as a washer between a screw and plate as previously described:

7.2 grams of pyrolytic carbon, 1.4 grams Teflon-6, and 12.4 grams Teflon-7 were mixed for three minutes.

This mixed product was filtered for six minutes.

The filter cake was compressed at 170°F. and 800 p.s.i. until the residual solvent was reduced to 11% by weight.

The filter cake thickness after compression was approximately 0.140 inch. The cake was run through the nip rolls or banded at a 220°F. roll temperature in decreasing steps of thickness as follows: 0.120, 0.100, 0.080, 0.060, 0.040, and 0.020 with a ninety degree alternation in direction of rolling between each step.

The rolling of the 0.020 inch stock at 340°F. was taken through four complete cycles of thickness reduction from 0.020 to 0.010 inch with the stock being folded double after each pass to provide the 0.020 inch thickness.

After sintering the member or washer so produced has been found to be suitable for use in implantation. It can be used to transmit the load for securing the plate 10 to the bone 14 by the screw 16. It does not extrude from its position between the screw shoulder 22 and the countersink 20. It also has suitable compressive strength and resiliency to assure that the outer surface layer of oxide coating on the screw shoulder 22 and the countersink 20 are not breached by the tightening of the screw 16 to secure the plate 10 in the desired position.

The polytetrafluoroethylene material is known to have low friction qualities and by properly embedding the solid particles in such material, the reduced friction property is maintained. With this material and the low friction it provides between the screw and plate, a smooth tightening is provided.

Thus, the present invention provides an improved bone fracture fixation appliance including an improved washer which is suitable for human implantation. This invention eliminates the corrosion of the implanted metal parts which results from the breaching of the surface oxide layer. By reducing corrosion, the problems associated with the release of metallic ions into the proximal tissues are eliminated.

WHAT WE CLAIM IS:—

1. An appliance suitable for surgical implantation for bone fracture fixation comprising, a corrosion resistant metal plate, and a corrosion resistant metal screw, said plate having at least one bore therethrough to receive said screw, and an annular inert load bearing washer bonded to said plate or said screw at a position to transmit the load between said plate and said screw and prevent abrasion of load transmitting surfaces of the plate and screw when said screw is tightened into bone.

2. An appliance according to claim 1, characterized in that said screw has a head defining a shoulder adapted to engage said plate around said bore, and said washer is bonded to said shoulder on said head of said screw.

3. An appliance according to claim 1 or 2 characterized in that said washer is a tetrafluoroethylene polymer having solids suspended therein.

4. An appliance according to claim 3, characterized in that said suspended solids are selected from a group consisting of particulate metal, fibrous metal, fibrous glass, fibrous quartz and particulate graphite.

5. An appliance according to claim 3 or 4 characterized in that the volume of solids in said washer is in the range of 15 percent to 50 percent of the washer volume.

6. An appliance according to claim 2, 3, 4 or 5, characterized by fluorinated ethylene propylene bonding said washer to said screw.

7. An appliance according to claim 3, 4 or 5 characterized in that each of said particles of fibers of said solid are uniformly mixed with said polymer.

8. An implantable bone fracture fixation appliance comprising, a corrosion resistant metal plate, a corrosion resistant metal screw, said plate having a bore therethrough to receive said screw, and an inert load bearing washer positioned between load transmitting surfaces of said screw and said plate whereby when said screw is tightened into bone, said washer remains between said surfaces and transmits the loading and prevents abrasion of the load transmitting surfaces when the screw is tightened into bone.

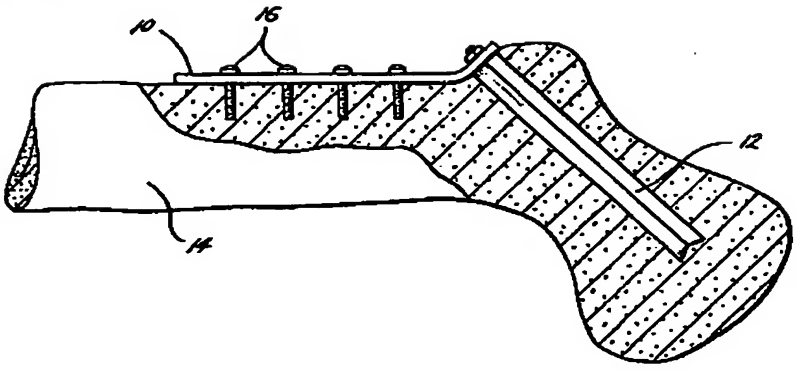
9. An appliance according to claim 1 substantially as shown and described.

POTTS, KERR & CO.

Printed for Her Majesty's Stationery Office by Burgess & Son (Abingdon), Ltd.—1972.
Published at The Patent Office, 25 Southampton Buildings, London, WC2A 1AY,
from which copies may be obtained.

1300449 COMPLETE SPECIFICATION
2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 1

Fig. 1



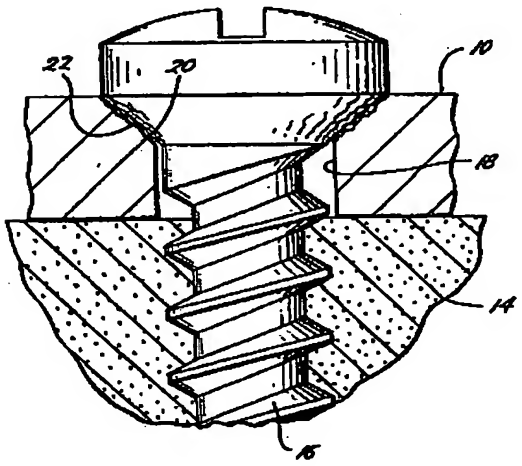


Fig. 2

1300449 COMPLETE SPECIFICATION
2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 2

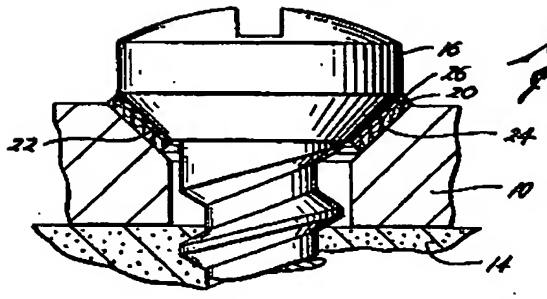


Fig. 3

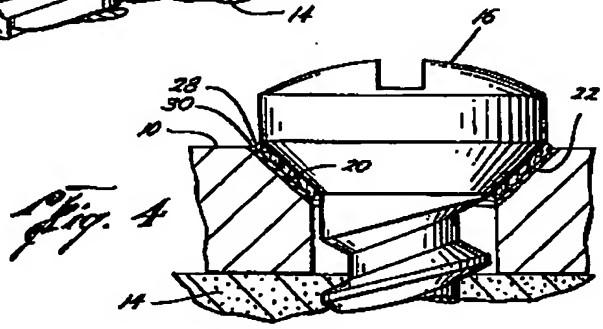


Fig. 4

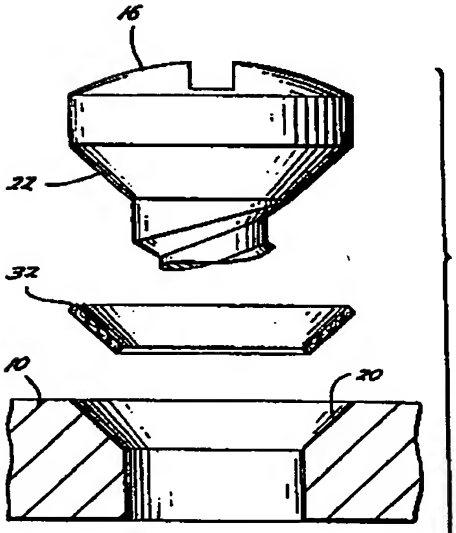


Fig. 5